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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,683

09/02/2005

Frederic Impellizzeri

1811-64

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EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

06/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,683	Applicant(s) IMPELLIZZERI, FREDERIC	
	Examiner MARY HOFFMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/07/2009, 12/04/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-21, 23, 25, 26 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-21, 23, 25, 26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Regarding Applicant's amendment to claim 28 including the term "constantly aligned," this term is not found in the specification to provide any kind of explanation as to its meaning. Based on Applicant's remarks, it appears that Applicant intends for this term to mean "fixed" and will be interpreted according for examination purposes.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-21, 23, 25 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the limitation

Art Unit: 3733

“uniform width” in claim 19, line 9. The inserts shown in the figures do not appear to be uniform in width; rather, the width appears to vary. In addition, the term “uniform width” is not disclosed in the specification. The term “uniform width” also appears in claim 28, line 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kummer et al. (U.S. Patent No. 4,338,926) in view of Frigg et al. (U.S. Patent No. 6,206,881).

Kummer et al. disclose a self-locking osteosynthesis device comprising a plate (ref. #1) having a plurality of openings formed therein, each of the plurality of openings having a diameter and an edge (see FIG. 4) forming a shoulder within the opening, the plate being formed of a metallic material; a plurality of inserts (see FIG. 4 ref. #'s 31-34) respectively fixedly and non-rotationally received in the plurality of openings (when the screw is inserted), each of the plurality of inserts defining a hole having an wall and a diameter less than the diameter of the opening, each of the plurality of inserts being formed of a biocompatible polymeric material, each insert fixedly engaging opposite surfaces of the shoulder of the opening, a plurality of bone screws respectively received in the hole of the plurality of inserts, the plurality of bone screws having a thread (see

Art Unit: 3733

ref. #'s 4-7) on an outer surface thereof, the biocompatible polymeric material being suitable for, or capable of, allowing a self-tapping of the smooth wall of the hole with the thread of the plurality of bone screws, and the bone screws having a head locked in the plurality of inserts when the thread of the bone screw engages an underlying surface.

The plurality of inserts being mechanically secured in the plurality of openings.

Kummer et al. disclose the claimed invention except for each tapping bone screw head having a conical shape and conical threading allowing the bone screw to be angularly received into threaded conical openings; and tapping the openings (i.e. the inner threads being positioned by the conical threading of the tapping screw head)

Frigg et al. disclose tapping bone screw heads having a conical shape and conical threading allowing the bone screws to be angularly received into threaded conical openings to achieve locking even when the bone screw is imperfectly inserted coaxially (see FIG. 1-2, col. 2, lines 1-7 and line 24).

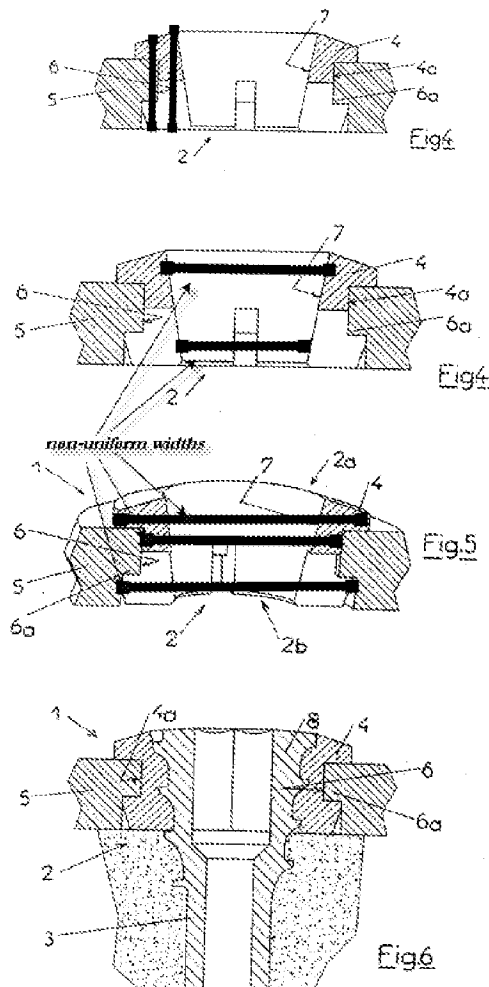
It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Kummer et al. with tapping bone screw heads having a conical shape and conical threading allowing the bone screw to be angularly received into threaded conical openings in view of Frigg et al. to achieve locking even when the bone screw is imperfectly inserted coaxially.

Response to Arguments

Applicant's arguments filed 12/04/2008 have been fully considered but they are not persuasive.

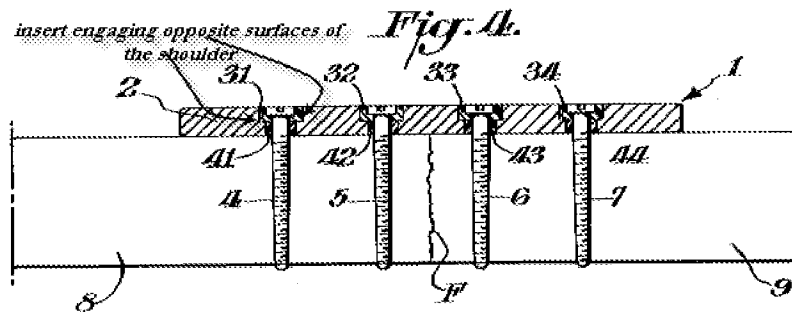
Art Unit: 3733

Applicant argues that the insert width is disclosed as uniform in FIGS. 4-6. If the examiner is misinterpreting Applicant's claims and arguments, the Applicant should further clarify. As shown below, the insert does not appear to have any uniform width. Rather, the width appears variable.



Applicant argues also argues that Kummer et al. in view of Frigg et al. does not disclose the claimed insert/shoulder engagement and the claimed self-tapping positioning. Regarding Applicant's argument that Kummer et al. in view of Frigg does not show that each insert fixedly engages opposite surfaces of the shoulder of the

opening, the examiner respectfully disagrees. As seen below, the insert clearly engages opposite surfaces of the shoulder.



Regarding Applicant's argument that Kummer et al. in view of Frigg does not show the claimed self-tapped positioning, the examiner respectfully disagrees. As seen below, the Frigg reference discloses self-tapping ability.

US 6,206,881 B1

2

The structured lateral surface 7 of head 5 of each bone screw 4 has greater hardness than the material in the vicinity of plate holes 3 in bone plate 1. As a result, even when bone screws 4 are inserted in an imperfectly coaxial manner into plate holes 3, optimal geometric locking is achieved because the harder, structured lateral surface 7 is able to penetrate the softer material of plate hole 3.

As shown in FIG. 3, plate holes 3 also may be fitted with threads 8. Advantageously, the two threads 8 and 9 will match one another. Advantageously, in such a combination threads 9 of heads 5 of bone screws 4 will have two or more turns engaging threads 8 of plate holes 3.

Thus, the combination of Kummer et al. in view of Frigg meets the claim language.

The rejections are deemed proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MARY HOFFMAN** whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733